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Project #52: Process Improvement in Interventional Research Through Utilization of a Clinical Trials Management System (CTMS)

Kenneth Winters
Henry Ford Health

Hannah Eaton
Henry Ford Health

Travis Wheeler
Henry Ford Health

Amanda Wigand
Henry Ford Health

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Ken Winters RN BSN, Hannah Eaton, Travis Wheeler, Amanda Wigand MS

Research Administration, Henry Ford Health, Detroit, Michigan

Abstract

•**Introduction:** Until recently, the management of clinical trials at Henry Ford Health has been largely decentralized, creating a disparity in trial administration and oversight from study to study. Individual departments and study teams were responsible for determining how their interventional research would be organized and conducted. This led to a vast variation in the way that Henry Ford researchers tracked and maintained research portfolios, study records, subject participation, as well as budgeting and invoicing practices. This autonomy also created further difficulties in compiling pragmatic research metrics, and a challenge in recognizing the full extent of the interventional research being conducted at a system level (1).

In an effort to standardize and unify interventional research across the system, Henry Ford Health - Research Administration began the process of implementing a Clinical Trials Management System (CTMS) across all research units that conduct interventional clinical trials. A CTMS provides the opportunity for a standardized structure for tracking study activity, maintaining regulatory documents, invoicing for research efforts, and ultimately offers a platform for recognizing clinical trial activity at both the department and system level (2).

While the implementation of the CTMS is still ongoing, and an ultimate understanding of this initiative's success is yet to be seen; an early indicator of the system's potential effectiveness is the real and perceived benefit experienced by newly trained end-users of the platform (3). As a very early measure of the gains experienced through this system, a survey was conducted with the currently active CTMS end-users, asking about any real or perceived benefit that the system may offer in helping conduct interventional research.

•**Methods:** A voluntary survey was sent to all end-users of the Oncore CTMS at Henry Ford Health via a web-based survey platform. The population of end-users surveyed consisted of research staff involved in interventional clinical trial research and was made up of Principal Investigators, Sub Investigators, Research Coordinator, Research Nurses Regulatory Coordinators and Financial Coordinators. The survey asked the end-user to answer 5 yes or no questions about real and perceived benefits of utilizing the Oncore CTMS. The results of the survey were compiled and classified as either a positive or negative metric of perceived usefulness.

•**Results:** Thirty-five Oncore CTMS end-users participated in the voluntary survey. All five survey questions yielded results that suggest that system end-users believed the implementation of the Oncore CTMS provided a perceived benefit. The survey results showed that 66% of respondents felt that oncore improved communication within their team, 86% felt they benefited from using Oncore CTMS, 83% believed that Oncore CTMS positively affected their workflow or team process; 71% have felt that Oncore CTMS improved the organization of protocol related items; and 91% believed that Oncore CTMS has the potential to improve their departments workflow in the future.

•**Conclusions:** While perceived benefit is just one metric measured in the constructs utilized to determine the success of information systems like a CTMS (3), and on its own does not prove the value of a system, it does offer the opportunity to gain an early glimpse of systems potential usefulness. It is understood that no relevant conclusions can be drawn about the successes of implementing a CTMS based upon the perceived benefit alone, and that additional research will need to be conducted after the system implementation is completed.

Overall System Initiatives

- Enterprise-wide reporting and visibility
- Streamline financial management
  - Standardize budgeting processes to optimize remuneration
  - Standardize coverage analysis process which will promote compliance with federal billing requirements
- Facilitate subject tracking
  - Timely subject visit tracking
  - Linking visits with invoices
- Optimize research workflows
  - Centralize research processes
  - Complete end to end workflow mapping
  - Create training materials to allow for consistent training
  - Reporting on compliance and performance

Pre-CTMS workflows

- Many research departments at Henry Ford were siloed, utilizing their own workflows and home-grown tracking documents to manage clinical trials.
- Standardized tracking and centralized oversight was not possible due to each department having different standards and expectations.
- Invoices were generated randomly and not always tracked to determine assure timely receipt of payment.
- Protocol documents (protocols, investigational brochures, consent forms) were filed in a shared drive or printed and stored in file cabinets.
- Subject visits were tracked by coordinators in Excel. Finance coordinators then used that and epic to determine what could be invoiced to sponsors.
- When research payments were received by HF, a mass email would be sent out to determine which grant/ department the payment belonged to.

Perceived Benefit

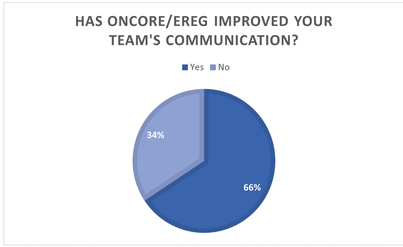

Figure 1: 66% of survey participants feel that OnCore/eReg has improved their team's communication.

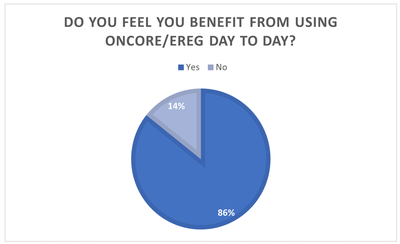

Figure 2: 86% of survey responders feel that they are benefitting from utilizing OnCore /eReg.

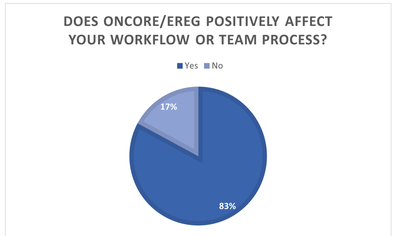

Figure 3: 83% of survey responders feel that OnCore/eReg has positively impacted their workflow and team process

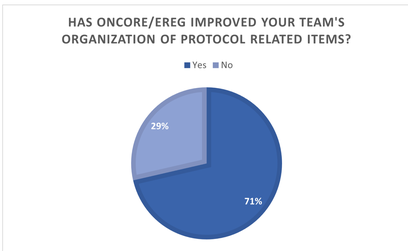

Figure 4: 71% of survey responders feel that OnCore/eReg has improved their organization.

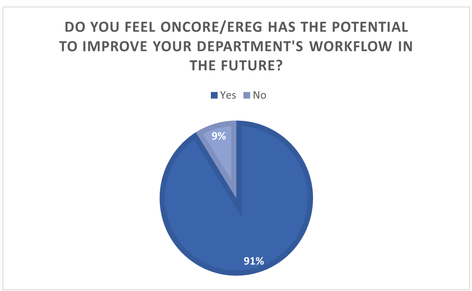

Figure 5: 91% of survey responders believe that OnCore/eReg have to potential to improve their team's workflow in the future

Where HF is headed

- ~80% of the HF Medical Group is utilizing standardized workflows within OnCore.
- Central leadership oversight of system research activities through reporting which was historically unavailable.
- Streamlined invoice and payment processing for all departments, leading to a decrease in monies landing in the T9 account each month.
- Standardized workflow for filing and accessibility of protocol documents.

Changes made to training over time

- New hire training was offered more frequently, which was previously only offered monthly.
- The implementation team developed and implemented a standard training schedule that covered main tasks and duties to help team members understand which functions they would be responsible for.
- Following each training, helpful documents and instruction manuals were distributed to attendees to reinforce lessons.

Challenges faced during implementation

- Implementation training was intensive and required teams to attend in-person.
- Being available for trainings and meetings was difficult and a burden for smaller teams.
- Lack of engagement within a team or willingness to change

Acknowledgments

We would like to acknowledge the clinical researchers that have been working with us to transition their workflows to include OnCore. Change is never an easy thing, but this has been taken in stride. The suggestions from all teams, will help OnCore and eRegulatory become customized tools for all of Henry Ford.

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